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|--|-------------|----------------------|------------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
| 10/590,595   | 10/20/2006  | Dominique Petit      | BDM-06-1251            | 8971             |
| 35811 7590 09/22/2009<br>IP GROUP OF DLA PIPER LLP (US)<br>ONE LIBERTY PLACE<br>1650 MARKET ST, SUITE 4900<br>PHILADELPHIA, PA 19103 |             |                      | EXAMINER               |                  |
|  |             |                      | HARVEY, JULIANNA NANCY |                  |
|  |             |                      | ART UNIT               | PAPER NUMBER     |
|  |             |                      | 3733                   |                  |
| NOTIFICATION DATE  |             | DELIVERY MODE        |                        |                  |
| 09/22/2009   |             | ELECTRONIC           |                        |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[pto.phil@dlapiper.com](mailto:pto.phil@dlapiper.com)

|                              |                                       |                                     |
|------------------------------|---------------------------------------|-------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/590,595  | <b>Applicant(s)</b><br>PETIT ET AL. |
|                              | <b>Examiner</b><br>Julianne N. Harvey | <b>Art Unit</b><br>3733             |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 October 2006.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 20-38 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 20-38 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 24 August 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-166/08)  
 Paper No(s)/Mail Date 24 Aug. 2006

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the through cavity (claim 22), the layer of six strands around a central strand (claim 26), the two layers of strands, one with six and one with 12 (claim 27), the strands twisted around the central strand (claim 28) –note that some of these features may be shown in a different embodiment of connecting element, but not in the claimed embodiment-- must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites that the strands of the layer or layers can be made of titanium-nickel alloy. However, the specification only states that the central strand may be made of such material, not the strands of the layer or layers. Since the examiner has not been provided with a translation of Applicant's foreign priority document (FR 04/02150), the examiner is taking the position that claim 31 contains new matter that was not previously disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 27, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites the limitation "the central strand" in line 2. Claim 27 recites the limitation "the central strand" in lines 2 and 3. Claim 32 recites the limitation "the central strand" in line 1. Claim 33 recites the limitation "the central strand" in line 1. Claim 34 recites the limitation "the central strand" in line 1. There is insufficient antecedent basis for this limitation in these claims as claim 20 does not recite a central strand.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 22, 23, 26-28, 32, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner et al. (EP 0 669 109 A1) (cited by Applicant on the 24 August 2006 IDS). Regarding **claim 20**, Baumgartner et al. disclose a connecting element (1, 10) for a spinal fixing system that connects at least two implantable connection assemblies (2, 3) comprising: a rod (1, 10) comprising a flexible part (1) extended at one end at least by a rigid part (10; col. 3, line 50 through col. 4, line 9 state that 10 can be rigid), the flexible part (1) comprising a cable (see cross-section 11 for the cable) at least partly surrounded by a polymer envelope (col. 3, line 50 through col. 4, line 9 state that the envelope can be a polymer), the cable comprising at least one elastic strand coaxial with the envelope (Fig. 6). Regarding **claim 22**, Baumgartner et al. disclose that the rigid part (10) has a through cavity (9) that at least partly receives

the cable (Fig. 6). Regarding **claim 23**, Baumgartner et al. disclose that the cavity (9) is configured to cooperate with the cable (Fig. 6). Regarding **claim 26**, Baumgartner et al. disclose that the cable comprises at least one layer of at least 6 strands (see cross-section 11), the strands being distributed around a central strand (Fig. 6). Regarding **claim 27**, Baumgartner et al. disclose that the cable comprises two successive layers of strands disposed around a central strand, the first layer of strands surrounding the central strand comprising 6 strands, the second layer of strands surrounding the first layer comprising 12 strands (see cross-section 11) (Fig. 6). Regarding **claim 28**, Baumgartner et al. disclose that the strands constituting the layer or layers comprises strands twisted around the central strand (col. 5, lines 46-58 state that the strands can be braided). Regarding **claim 32**, Baumgartner et al. disclose that the strand is tubular (see cross-section 11) (Fig. 6). Regarding **claim 38**, Baumgartner et al. disclose a spinal fixing system comprising at least two implantable connection assemblies (2, 3) connected by at least one connecting element (1, 10) according to claim 20 (see claim 20 above) (Fig. 6).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-27, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Baumgartner et al. (EP 0

669 109 A1). Regarding **claim 20**, Jahng discloses a connecting element (4) for a spinal fixing system that connects at least two implantable connection assemblies (2) comprising: a rod (4) comprising a flexible part (8) extended at one end at least by a rigid part (9), the flexible part (8) comprising a cable (32) at least partly surrounded by an envelope (5), the cable (32) comprising at least one elastic strand (para. 0080) coaxial with the envelope (Figs. 2, 5, 7, and 9). Regarding **claim 21**, Jahng discloses that the rigid part (9) has a blind cavity that at least partly receives the cable (32) (Fig. 7; paras. 0076 and 0078). Regarding **claim 22**, Jahng discloses that the rigid part (9) has a through cavity that at least partly receives the cable (32) (Fig. 5; para. 0076). Regarding **claim 23**, Jahng discloses that the cavity is configured to cooperate with the cable (32) (Figs. 5 and 7). Regarding **claim 24**, Jahng discloses that the cavity has a zone widened in the direction of an end receiving the cable (32) (Figs. 5 and 7). Regarding **claim 25**, Jahng discloses that the flexible part (8) is fixed to the rigid part (9) by adhesive bonding, crimping, or welding (para. 0076). Regarding **claim 31**, Jahng discloses that the strands are made of titanium or stainless steel or titanium-nickel alloy (para. 0080). Jahng fails to disclose that the envelope is a polymer envelope (**claim 20**), that the cable comprises at least one layer of at least six strands distributed around a central strand (**claim 26**), that the cable comprises two layers of strands, the first layer surrounding a central strand and comprising six strands, the second layer surrounding the first layer and comprising twelve strands (**claim 27**), and that the strands of the layer or layers are formed from a material different from that of a central strand (**claim 29**). However, Jahng states that the number of strands can be varied to provide a desired

rigidity and flexibility in accordance with a patient's particular needs (para. 0080). Baumgartner et al. teach a connecting element (1, 10) comprising a flexible part (1) comprising a cable (see cross-section 11 for the cable) at least partly surrounded by a polymer envelope (col. 3, line 50 through col. 4, line 9 state that the envelope can be a polymer) (Fig. 6). The cable of Baumgartner et al. comprises two successive layers of strands disposed around a central strand, the first layer of strands surrounding the central strand comprising 6 strands, the second layer of strands surrounding the first layer comprising 12 strands (see cross-section 11) (Fig. 6). It would have been obvious to one having ordinary skill in the art at the time the invention was for the envelope of Jahng to be a polymer envelope (**claim 20**), as suggested by Baumgartner et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It would have been obvious to one of ordinary skill in the art at the time the invention was made for the cable to comprise at least one layer of at least six strands distributed around a central strand (**claim 26**), and for the cable to comprise two layers of strands, the first layer surrounding a central strand and comprising six strands, the second layer surrounding the first layer and comprising twelve strands (**claim 27**), as suggested by Baumgartner et al., since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, such would be obvious because, as stated by Jahng, the number of strands can be varied to provide a desired rigidity and flexibility in accordance with a patient's particular

needs (para. 0080). It would have been obvious to one having ordinary skill in the art at the time the invention was for the strands of the layer or layers to be formed from a material different from that of a central strand (**claim 29**), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

**Claim 30** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Baumgartner et al. (EP 0 669 109 A1) as applied to claims 26 and 27 above, and further in view of Mazel (US 5,704,936 A). Jahng and Baumgartner et al. teach the claimed invention except that a central strand has a diameter different from that of strands of the layer or layers. Mazel teaches a rod (87) comprising strands (88) wherein a central strand has a diameter different from that of the strands surrounding it (Figs. 27 and 28). It would have been an obvious matter of design choice for a central strand to have a diameter different from that of strands of the layer or layers, as suggested by Mazel, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 20, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Baumgartner et al. (EP 0 669 109 A1). Regarding **claim 20**, Jahng discloses a connecting element (4) for a spinal fixing system that connects at least two implantable connection assemblies (2)

comprising: a rod (4) comprising a flexible part (8) extended at one end at least by a rigid part (9), the flexible part (8) comprising a cable (34) at least partly surrounded by an envelope (5), the cable (34) comprising at least one elastic strand (para. 0081) coaxial with the envelope (Figs. 2, 5, 7, and 10). Regarding **claim 33**, Jahng discloses that the strand is formed from an alloy of nickel-titanium, titanium, stainless steel, or polymer (para. 0081). Regarding **claim 34**, Jahng discloses that the strand is made from PEEK or polyurethane (para. 0081). Jahng fails to disclose that the envelope is a polymer envelope (**claim 20**). Baumgartner et al. teach a connecting element (1, 10) comprising a flexible part (1) comprising a cable (see cross-section 11 for the cable) at least partly surrounded by a polymer envelope (col. 3, line 50 through col. 4, line 9 state that the envelope can be a polymer) (Fig. 6). It would have been obvious to one having ordinary skill in the art at the time the invention was for the envelope of Jahng to be a polymer envelope (**claim 20**), as suggested by Baumgartner et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

**Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Baumgartner et al. (EP 0 669 109 A1) as applied to claim 20 above, and further in view of Freudiger (US 2003/0220642 A1). Jahng and Baumgartner et al. teach the claimed invention except that the envelope is made from polyurethane. Freudiger teaches a flexible rod wherein the rod is made of polyurethane (para. 0013). It would have been obvious to one having ordinary skill in the art at the

time the invention was for the envelope of Jahng to be made from polyurethane, as suggested by Freudiger, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

**Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Baumgartner et al. (EP 0 669 109 A1) as applied to claim 20 above, and further in view of Sherman et al. (US 2005/0085814 A1). Jahng and Baumgartner et al. teach the claimed invention except that the envelope is made from PEEK. Sherman et al. teach a flexible rod wherein the rod is made of PEEK (para. 0031). It would have been obvious to one having ordinary skill in the art at the time the invention was for the envelope of Jahng to be made from PEEK, as suggested by Sherman et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

**Claim 37** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Baumgartner et al. (EP 0 669 109 A1) as applied to claim 20 above, and further in view of Trieu et al. (US 2002/0120270 A1). Jahng and Baumgartner et al. teach the claimed invention except that the envelope is made of a biocompatible fabric. Trieu et al. teach a flexible implant wherein the implant is made of a biocompatible fabric (para. 0035). It would have been obvious to one having ordinary skill in the art at the time the invention was for the envelope of Jahng to be made from a biocompatible fabric, as suggested by Trieu et al., since it has been held to be within the

Art Unit: 3733

general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 8:00 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./  
Examiner, Art Unit 3733  
/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733

Application/Control Number: 10/590,595

Art Unit: 3733

Page 12